

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BTL INDUSTRIES, INC.,

Plaintiff,

v.

**ALLERGAN LIMITED, ALLERGAN USA,
INC., ALLERGAN, INC., ZELTIQ
AESTHETICS, INC., ZELTIQ IRELAND
UNLIMITED COMPANY, and ZIMMER
MEDIZINSYSTEME GMBH,**

Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff BTL Industries, Inc. (BTL), by its attorneys, for its complaint against Allergan Limited, Allergan USA, Inc., Allergan, Inc. (collectively, “Allergan”), Zeltiq Aesthetics, Inc. (Zeltiq USA), Zeltiq Ireland Unlimited Company (Zeltiq Ireland) (collectively, “Zeltiq”), and Zimmer MedizinSysteme GmbH (Zimmer) (collectively, “Defendants”), alleges as follows:

NATURE OF THE SUIT

1. This is a civil action arising out of Defendants’ patent infringement in violation of the patent laws of the United States, 35 U.S.C. §§ 271 and 281–285.

PARTIES

2. BTL is a privately held corporation organized and existing under the laws of Delaware with a principal place of business at 362 Elm Street, Marlborough, Massachusetts 01752.

3. On information and belief, Allergan Limited, formerly known as Allergan plc, is an Irish corporation with its principal place of business at Clonsaugh Business and Technology

Park, Coolock, Dublin, D17 E400, Ireland. On information and belief, Allergan plc is an affiliate of Allergan USA, Inc., Allergan, Inc., Zeltiq USA, and Zeltiq Ireland.

4. On information and belief, Allergan USA, Inc. (Allergan USA) is a corporation organized and existing under the laws of Delaware with a place of business at 5 Giralda Farms, Madison, New Jersey 07940. On information and belief, Allergan USA is an affiliate of Allergan Limited, Allergan, Inc., Zeltiq USA, and Zeltiq Ireland.

5. On information and belief, Allergan, Inc. is a corporation organized and existing under the laws of Delaware with a place of business at 5 Giralda Farms, Madison, New Jersey 07940. On information and belief, Allergan, Inc. is an affiliate of Allergan Limited, Allergan USA, Zeltiq USA, and Zeltiq Ireland.

6. On information and belief, Zeltiq USA is a corporation organized and existing under the laws of Delaware with a principal place of business at 4410 Rosewood Dr., Pleasanton, California 94588-3050. On information and belief, Zeltiq USA is an affiliate of Allergan Limited, Allergan USA, Allergan, Inc., and Zeltiq Ireland.

7. On information and belief, Zeltiq Ireland is an Irish corporation with its principal place of business at Galway West Business Park, Western Distributor Road, Knocknacarra, Galway H91E8C3, Ireland. On information and belief, Zeltiq Ireland is an affiliate of Allergan Limited, Allergan USA, Allergan, Inc., and Zeltiq USA.

8. On information and belief, Zimmer is a company organized and existing under the laws of Germany with its principal place of business at Junkersstraße 9, 89231 Neu-Ulm, Germany.

9. On information and belief, Allergan Limited, Allergan USA, Allergan, Inc., Zeltiq USA, Zeltiq Ireland, and Zimmer acted in concert to commit the acts complained of herein. For

example, Zimmer manufactures and imports the CoolTone product and Allergan and Zeltiq offer for sale and sell the CoolTone product and its components and the CoolSculpting product and its components (“Accused Products”) as part of a “Trusted Allergan Partnership,” in which doctors and patients benefit from the “confidence inherent in a trusted Allergan partnership and unprecedented benefits.” *See* Exhibits 1–3. Allergan and Zeltiq also promote, encourage, direct, and instruct customer-physicians or other medical professionals to use the Accused Products in an infringing manner.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Allergan Limited because, upon information and belief, acting in concert with the other Defendants, Allergan Limited imports, offers for sale, sells, and distributes the Accused Products and their components in the United States knowing that they will be offered for sale, sold, and used in Delaware, made the Accused Products available for sale in Delaware through an established distribution chain, and BTL’s cause of action for patent infringement arises out of these activities. *See* Exhibits 4–6. On information and belief, Allergan Limited has derived, and will derive, substantial revenue from the sale of the Accused Products in Delaware.

12. This Court has personal jurisdiction over Allergan USA because, among other things, Allergan USA is a corporation formed under the laws of the State of Delaware and has registered to do business in the State of Delaware. Allergan USA has thus consented to jurisdiction in Delaware.

13. In addition, this Court has personal jurisdiction over Allergan USA because Allergan USA has committed an act of patent infringement under 35 U.S.C. § 271(a), (b), or (c) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to BTL in Delaware. For example, on information and belief, acting in concert with the other Defendants, Allergan USA imports, offers for sale, sells, and distributes its products in the United States and this District, including but not limited to, the Accused Products.

14. This Court also has personal jurisdiction over Allergan USA because Allergan USA has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Allergan USA regularly and continuously transacts business within Delaware, including the offer to sell or selling the Accused Products in Delaware. On information and belief, Allergan USA continuously places its products into the stream of commerce, including the distribution and consumption in Delaware and throughout the United States and BTL's cause of action for patent infringement arises from these actions. On information and belief, Allergan USA has derived, and will derive, substantial revenue from the sale of the Accused Products in Delaware.

15. This Court has personal jurisdiction over Allergan, Inc. because, among other things, Allergan, Inc. is a corporation formed under the laws of the State of Delaware and has registered to do business in the State of Delaware. Allergan, Inc. has thus consented to jurisdiction in Delaware.

16. In addition, this Court has personal jurisdiction over Allergan, Inc. because Allergan, Inc. has committed an act of patent infringement under 35 U.S.C. § 271(a), (b), or (c) and intends a future course of conduct that includes acts of patent infringement in Delaware.

These acts have led and will lead to foreseeable harm and injury to BTL in Delaware. For example, on information and belief, acting in concert with the other Defendants, Allergan, Inc. offers for sale, sells, and distributes its products in the United States and this District, including but not limited to, the Accused Products. *See* Exhibits 4–5. The CoolTone and CoolSculpting product websites use and display Allergan, Inc.’s trademark. *See* Exhibits 8–9.



The content of this Website is intended for informational purposes only and should not be used as a substitute for advice provided by a qualified healthcare professional. The Website serves as a resource platform for clinicians to assist clinics in integrating CoolSculpting® into their practice.

COOLSCULPTING®, the Snowflake Design, and COOLTONE™ are trademarks of ZELTIQ Aesthetics, Inc., an Allergan affiliate. Allergan® and its design are trademarks of Allergan, Inc. All other trademarks are the property of their respective owners. © 2020 Allergan. All rights reserved.

Allergan, 4410 Rosewood Drive, Pleasanton, CA 94588

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17. This Court also has personal jurisdiction over Allergan, Inc. because Allergan, Inc. has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Allergan, Inc. regularly and continuously transacts business within Delaware, including the offer to sell or selling the Accused Products in Delaware. On information and belief, Allergan, Inc. continuously places its products into the stream of commerce, including the distribution and consumption in Delaware and throughout the United States, and BTL’s cause of action for patent infringement arises from these actions. On information and belief, Allergan, Inc. has derived, and will derive, substantial revenue from the sale of the Accused Products in Delaware.

18. This Court has personal jurisdiction over Zeltiq USA because, among other things, Zeltiq USA is a corporation formed under the laws of the State of Delaware and has registered to do business in the State of Delaware. Zeltiq USA has thus consented to jurisdiction in Delaware.

19. In addition, this Court has personal jurisdiction over Zeltiq USA because Zeltiq USA has committed an act of patent infringement under 35 U.S.C. § 271(a), (b), or (c) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to BTL in Delaware. For example, on information and belief, acting in concert with the other Defendants, Zeltiq USA imports, offers for sale, sells, and distributes its products in the United States and this District, including but not limited to, the Accused Products. *See* Exhibits 4–5. On information and belief, Zeltiq USA filed a 510(k) application for the CoolSculpting product with the Food and Drug Administration (FDA) “to notify FDA of their intent to market” the CoolSculpting product in the United States and Delaware. U.S. Food & Drug Administration, 510(k) Clearances (citations omitted). The CoolTone and CoolSculpting product websites also use Zeltiq USA’s CoolTone and CoolSculpting trademarks and display the company’s address at 4410 Rosewood Drive, Pleasanton, CA 94588. *See* Exhibits 8–9.

20. This Court also has personal jurisdiction over Zeltiq USA because Zeltiq USA has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Zeltiq USA regularly and continuously transacts business within Delaware, including the offer to sell or selling the Accused Products in Delaware. On information and belief, Zeltiq USA continuously places its products into the stream of commerce, including distribution and consumption in Delaware and throughout the United States, and BTL’s cause of action for patent infringement arises from these actions. On information and belief, Zeltiq USA has derived, and will derive, substantial revenue from the sale of the Accused Products in Delaware.

21. This Court has personal jurisdiction over Zeltiq Ireland because, upon information and belief, acting in concert with the other Defendants, Zeltiq Ireland has purposefully manufactured and imported the CoolSculpting product and its components into the United States knowing that it will be offered for sale, sold, and used in Delaware, made the product available for sale in Delaware through an established distribution chain, and BTL's cause of action for patent infringement arises out of these activities. *See* Exhibit 5. On information and belief, Zeltiq Ireland is registered with the FDA as the manufacturer of the CoolSculpting product and accessories, including pads and gels. Exhibits 10–11. On information and belief, Zeltiq Ireland also ships the CoolSculpting product and accessories to the United States. Exhibits 12–13. On information and belief, Zeltiq Ireland has derived, and will derive, substantial revenue from the sale of the CoolTone product in Delaware.

22. This Court has personal jurisdiction over Zimmer because, upon information and belief, Zimmer, acting in concert with the other Defendants, has purposefully manufactured and imported the CoolTone product into the United States knowing that it will be offered for sale, sold, and used in Delaware, made those products available for sale in Delaware through an established distribution chain, and BTL's cause of action for patent infringement arises out of these activities. On information and belief, Zimmer filed a 510(k) application for the CoolTone product with the FDA “to demonstrate that the device to be marketed is [at least] as safe and effective, that is, substantially equivalent, to a legally marketed device . . . that is not subject to premarket approval.” U.S. Food & Drug Administration, 510(k) Premarket Notification (citations omitted). On information and belief, Zimmer began importing the CoolTone product into the United States on or around May 2020. Exhibit 7. On information and belief, Zimmer has derived, and will derive, substantial revenue from the sale of the CoolTone product in Delaware.

23. Venue is proper in this District under 28 U.S.C. § 1400 and 28 U.S.C. § 1391.

BACKGROUND

24. Since its founding in 2008, BTL has been a world leader and innovator in the field of non-invasive body-contouring and physiotherapy. *See, e.g.*, Exhibit 14. As relevant here, BTL and its affiliates developed proprietary technology that uses high-intensity, focused electromagnetic energy to tone muscles in patients for aesthetic purposes. *See id.* After years of research and development, BTL and its affiliates successfully incorporated this technology into a standalone, non-invasive, aesthetic body-contouring apparatus known as the Emsculpt® device.



25. In June 2018, BTL received clearance from the FDA for its Emsculpt device with large applicators and began to sell the device in the United States for the improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen, and for strengthening, toning, and firming buttocks and thighs. Exhibit 15. In October 2018, BTL received FDA clearance for an additional indication for the improvement of muscle tone and

firmness in arms. Exhibit 16. In July 2019, BTL received FDA clearance for the Emsculpt device with both large and small applicators for the improvement of abdominal tone, strengthening of abdominal muscles, development of firmer abdomen, strengthening, toning and firming of buttocks, thighs and calves, as well as improvement of muscle tone and firmness, for strengthening muscles in arms. Exhibit 17.

26. BTL continues to market and distribute the Emsculpt device throughout the United States. Until recently, BTL's Emsculpt device was the only FDA-cleared non-invasive, body-contouring device that applied high-intensity, focused electromagnetic energy for aesthetic purposes that was marketed and sold in the United States.

27. BTL's Emsculpt device uses two applicators to induce powerful muscle contractions in a patient. BTL has invested its resources to develop optimal shapes and sizes for Emsculpt applicators, tailoring each type of applicator to a specific area to be targeted. For example, applicators intended for use to tone the abdomen or buttocks differ in size and shape to the applicators intended for use on legs and arms.

28. BTL has also invested time and effort developing protocols for aesthetic therapies using the Emsculpt device. For example, BTL researched the safety and performance of high intensity, focused electromagnetic energy to optimize treatment protocols that result in increased muscle tone. BTL's proprietary protocols create repetitive muscle contractions that result in a non-invasive method of toning muscle and body sculpting for aesthetic purposes.

29. Before BTL launched the Emsculpt device in 2018, no other product used high intensity, focused electromagnetic energy to tone and firm muscle for non-invasive body-contouring. Prior devices in the aesthetics market used different technology to burn fat or attack

cellulite. BTL's Emsculpt device thus created a new market in which it quickly became the innovative industry leader.

30. The aesthetic industry has recognized BTL's innovation, hailing it as having taken "the aesthetics industry by storm," praised BTL as being the first to apply high-intensity, focused electromagnetic energy technology for aesthetics, and lauding the Emsculpt device as having "transformed treatment protocols." *See* Exhibit 14. Patients identified BTL's Emsculpt treatments as one of the 2019 "Most Worth It Procedures." Exhibit 18; *see also* Exhibit 19. The Emsculpt device has been described as "revolutionary," and "[o]ne of the newest and most progressive body-shaping technologies" on the market. Exhibits 20–21.

31. BTL has also received a number of awards in the United States for the Emsculpt device, including NewBeauty 2019 Award Winner for Best Innovations and Best Body-Firming Treatment by Harper's Bazaar as part of its 2020 Anti-Aging Awards. *E.g.*, Exhibits 20, 22.

32. BTL's research and innovation has "revolutionized the aesthetics industry." Exhibit 19. BTL's market success and superior performance are by-products of technological innovations over the past several decades. BTL continues to implement these innovations today.

33. BTL holds an exclusive license to a patent portfolio that covers various aspects of its innovative non-invasive aesthetic body-contouring device including the Asserted Patents in this complaint. The Asserted Patents are directed to and protect the important innovative features embodied in BTL's Emsculpt device. These patented features have contributed to the success of the Emsculpt device in the United States and has allowed BTL to establish itself as a market leader.

THE ASSERTED PATENTS

34. On April 28, 2020, the United States Patent and Trademark Office (USPTO) duly and lawfully issued U.S. Patent No. 10,632,321 ("the '321 patent"), entitled "Aesthetic Method

of Biological Structure Treatment by Magnetic Field.” A true and correct copy of the ’321 patent is attached hereto as Exhibit 23.

35. On June 30, 2020, the USPTO duly and lawfully issued U.S. Patent No. 10,695,575 (“the ’575 patent”), entitled “Aesthetic Method of Biological Structure Treatment by Magnetic Field.” A true and correct copy of the ’575 patent is attached hereto as Exhibit 24.

36. On June 30, 2020, the USPTO duly and lawfully issued U.S. Patent No. 10,695,576 (“the ’576 patent”), entitled “Aesthetic Method of Biological Structure Treatment by Magnetic Field.” A true and correct copy of the ’576 patent is attached hereto as Exhibit 25.

37. On July 14, 2020, the USPTO duly and lawfully issued U.S. Patent No. 10,709,894 (“the ’894 patent”), entitled “Aesthetic Method of Biological Structure Treatment by Magnetic Field.” A true and correct copy of the ’894 patent is attached hereto as Exhibit 26.

38. On July 14, 2020, the USPTO duly and lawfully issued U.S. Patent No. 10,709,895 (“the ’895 patent”), entitled “Aesthetic Method of Biological Structure Treatment by Magnetic Field.” A true and correct copy of the ’895 patent is attached hereto as Exhibit 27.

39. BTL Medical Technologies s.r.o. obtained title to the Asserted Patents after a merger with Medical Technologies CZ a.s., wherein all assets of Medical Technologies CZ a.s. passed to BTL Medical Technologies s.r.o., including the Asserted Patents. The notice of merger is attached hereto as Exhibit 28. Medical Technologies CZ a.s. exclusively licensed the Asserted Patents to BTL. BTL possesses all substantial rights in the Asserted Patents, including the exclusive right to sue for infringement without joining the licensor and the exclusive right of recovery for any past, present, or future infringements of the Asserted Patents.

INFRINGEMENT CONDUCT

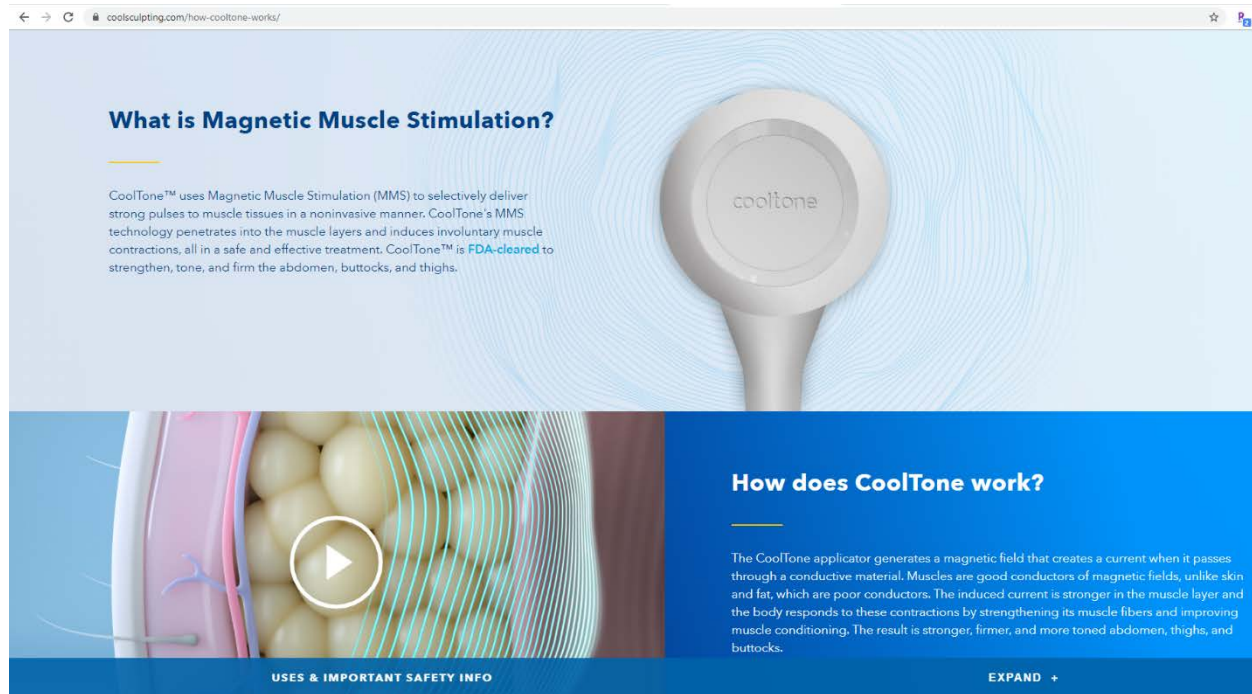
40. In contrast to BTL, Allergan is a newcomer to the non-invasive aesthetic body-contouring industry. On information and belief, Allergan entered the industry only recently in

2017 with Allergan Limited’s (previously Allergan plc) acquisition of Zeltiq. Exhibits 3, 29. On information and belief, prior to its acquisition, Zeltiq was selling its cooling fat-reducing product under the brand name CoolSculpting. Acquiring Zeltiq allowed Allergan to enter the body-contouring segment of the medical aesthetic market. *See id.* The Chief Commercial Officer of Allergan, Bill Meury, stated that the Zeltiq acquisition “immediately expands [Allergan’s] world-class global aesthetic business into the highly-complementary and fast-growing body contouring segment.” *Id.* Allergan and Zeltiq continued to manufacture and sell the CoolSculpting device in the United States after the acquisition and continue to do so today.

41. In 2019, Allergan and Zeltiq began to advertise a product that uses high-intensity, focused electromagnetic energy to tone muscles in patients for aesthetic purposes—its CoolTone product. Upon information and belief, starting in December 2019, in conjunction with Zimmer—the entity involved in manufacturing the CoolTone product—Allergan and Zeltiq began to import, offer to sell, and sell the CoolTone product in the United States.

The CoolTone Product

42. The CoolTone website explains that the CoolTone product uses “Magnetic Muscle Stimulation (MMS)” to “selectively deliver strong pulses to muscle tissues in a noninvasive manner. CoolTone’s MMS technology penetrates into the muscle layers and induces involuntary muscle contractions . . . to strengthen, tone, and firm the abdomen, buttocks, and thighs.” On information and belief, the CoolTone product and its methods of use infringe the Asserted Patents. *See, e.g.,* Exhibits 6, 30, 32.



43. The CoolTone 510(k) application states: “The CoolTone is a non-invasive therapeutic device. The device produces an electromagnetic field that interacts with the tissues of the human body. By muscle stimulation, the CoolTone helps to strengthen, tone and firm abdomen, buttocks and thighs. . . . Two large applicators are connected to the control unit and can be used simultaneously depending on the treatment. The device is a [sic] medical equipment that generates a magnetic field by applying a strong current to an applicator. The CoolTone is equipped with the securement system which is designed to maintain applicator position throughout treatment.” Exhibit 31. Zimmer’s 510(k) application also stated that the CoolTone product had treatment “parameters such as frequency, time and intensity” that can be administered using “[t]hree pre-set treatment options” for the abdomen, buttocks, and thighs. *Id.*

44. On information and belief, Defendants sell components of the CoolTone product, including for example, the main unit, applicators, straps, and virtual consumables, *i.e.*, treatment

cards that enable the CoolTone product to administer the treatment protocols that infringe the Asserted Patents.



45. On or about June 24, 2019, Allergan and Zeltiq announced FDA clearance of the CoolTone product. Exhibit 6. According to a June 24, 2019 press release, the “CoolTone device received FDA clearance for improvement of abdominal tone, strengthening of the abdominal muscles, and development for firmer abdomen. CoolTone is also indicated for strengthening, toning and firming of buttocks and thighs.” *Id.*

46. On information and belief, Defendants received FDA clearance for the CoolTone product on or about November 15, 2019. Exhibit 31. FDA cleared the CoolTone product for the following indications for use: “[i]mprovement of abdominal tone, strengthening of the abdominal muscles, development for firmer abdomen” and “[s]trengthening, [t]oning and [f]irming of buttocks and thighs.” *Id.*

47. On information and belief, in June 2019, Defendants began offering its CoolTone product for sale. For example, an Allergan press release dated June 24, 2019, states “Allergan is

now taking orders for the CoolTone device, and first units will ship early in the fourth quarter of this year.” Exhibit 6.

48. On information and belief, Defendants sell the CoolTone product in interstate commerce throughout the United States and Delaware. For example, Allergan has sold the CoolTone product to physicians in and around Delaware. These customer-physicians are listed on the CoolTone website as physicians who offer the CoolTone treatment. *See, e.g.*, Exhibit 5 (using the CoolTone “Find a Center” search engine to find CoolTone treatment providers in the Delaware area). For example, Delaware physician Dr. Bryan D. Seiff of Dover, Delaware offers the CoolTone treatment to patients. *Id.* On information and belief, Defendants continue to deliver the CoolTone product and components to clinics in the United States. Physicians and medical aestheticians across the United States offer CoolTone treatments. *See, e.g., id.*; Delaware Valley Plastic Surgery, <https://delawarevalleyplasticsurgery.com/cooltone-philadelphia/> (last visited July 7, 2020); Renove Med. Spa, <https://www.renovemedspa.org/cooltone> (last visited July 7, 2020); Best Impression Medical Spa and Laser Center, <https://www.bestimpressionmedspa.com/contents/non/body-procedures/cooltone> (last visited July 7, 2020); Berks Plastic Surgery, <https://www.berksplasticsurgery.com/body/cooltone-reading-pa/> (last visited July 7, 2020).

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OUR PATIENTS ARE SAYING

49. Defendants have imported into the United States and sold within the United States the CoolTone product to doctors for use on patients for non-invasive aesthetic body contouring. For example, on information and belief, Defendants imported the CoolTone product into the United States on or about May 16, 2020 and June 16, 2020. *See, e.g.*, Exhibit 7.

50. On information and belief, the CoolTone product includes or performs each and every limitation of at least one claim of each Asserted Patent, either literally or under the doctrine of equivalents. For example, when operated as intended, the CoolTone product infringes claim 1 of the '321 patent, which recites “A method for toning muscles of a patient using a treatment device that generates time-varying magnetic fields, the method comprising: . . . applying the plurality of consecutive impulses of the . . . time-varying magnetic field to muscle fibers . . . in the body region such that a first muscle and a second muscle of the body region are caused to contract.” *See also, e.g.*, claim 1 of the '575 patent (reciting similar language); claim 1 of the '895 patent. The CoolTone User Manual Foreword states: “The CoolTone System is intended to provide entirely non-invasive electromagnetic stimulation for: Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen,

[s]trengthening, toning and firming of buttocks and thighs.” Exhibit 32 at 7. The Foreword also states that the CoolTone product “repeatedly contracts muscle tissue.” *Id.*

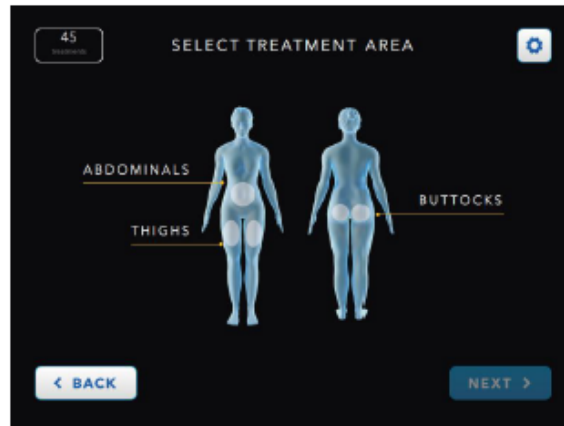
51. As another example, claim 1 of the ’576 patent recites, “A device for toning a muscle of a patient, comprising: a control unit. . . a first applicator . . . a second applicator . . . a belt . . . wherein the device is configured to apply . . . pulses to the body region to cause muscle contractions.” *See also, e.g.*, claim 1 of the ’894 patent (reciting similar language). The CoolTone User Manual lists the “Contents of the CoolTone™ System” as including “1 Control Unit,” “2 Applicators,” and “1 Securement system.” Exhibit 32 at 6; *see also id.* at 11, 13, 26.

52. On information and belief, Defendants actively direct, encourage, promote, distribute, provide instruction for, and support the use of the CoolTone product with the knowledge and intention that their customers will commit acts in such a manner that constitutes direct infringement of the method claims of the Asserted Patents. *See* Exhibit 8 (advertising CoolTone treatment to tone, firm, and strengthen abdomen, buttocks, and thighs using magnetic intensity); Exhibit 32. Specifically, Defendants provide a User Manual for the CoolTone System that explicitly instructs their customers to use the CoolTone product in a way that directly infringes the method claims of the Asserted Patents. Exhibit 32.

53. The CoolTone User Manual instructs the customer-physician to use the CoolTone product to administer treatments to patients. *Id.* at 17–23. For example, the CoolTone User Manual provides step-by-step instructions, starting with “[p]ressing [the] ‘New Treatment Button’” to start the treatment, “select[ing] one of the treatment areas: ‘Buttocks,’ ‘Abdominals,’ or ‘Thighs,’” preparing the applicators, securing and placing the applicators to the patient “over the desired treatment area(s),” and initiating treatment. *Id.* at 17–23, 26–29.

5. Select the Treatment Area

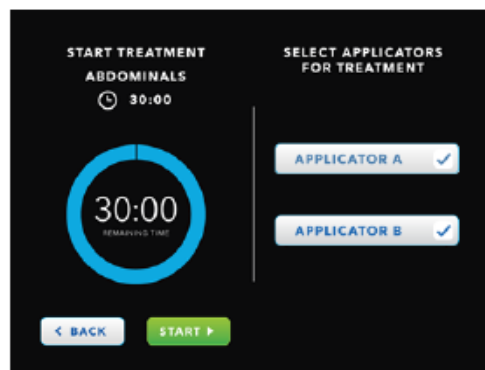
The user can select one of the treatment areas: "Buttocks," "Abdominals" or "Thighs" by pressing on the treatment area as indicated by the white circular regions.



A. Press "Next" to proceed to the Position Applicator screen

7. Start Treatment

Select the applicator(s) applied for treatment and start the treatment.



To select Applicator "A" or "B" or both "A" and "B":

Ensure that the Applicator box is checked. Default is unchecked blue box.



Press "Start" button to start the treatment

54. On information and belief, medical professionals directly infringe one or more claims of the Asserted Patents either literally or under the doctrine of equivalents when they treat patients using the CoolTone product in accordance with established treatment protocols. On

information and belief, the CoolTone product operates using treatment cards that are required to run the pre-programmed CoolTone protocols. On information and belief, the CoolTone product can provide treatment only by using these pre-programmed protocols. On information and belief, these pre-programmed protocols, when enacted, necessarily practice one or more claims of the Asserted Patents, either literally or under the doctrine of equivalents.

55. On information and belief, Defendants also contribute to the infringement of each of the '321, '575, and '895 patents by their importation, offer for sale, or sale within the United States of the CoolTone product and its components. On information and belief, Defendants are aware that their imported components are designed for use in the CoolTone product, embody a material part of the invention claimed in the Asserted Patents, and are not staple articles of commerce suitable for non-infringing use. On information and belief, the CoolTone product and its components have no substantial non-infringing use.

The use of the CoolTone product with the CoolSculpting product

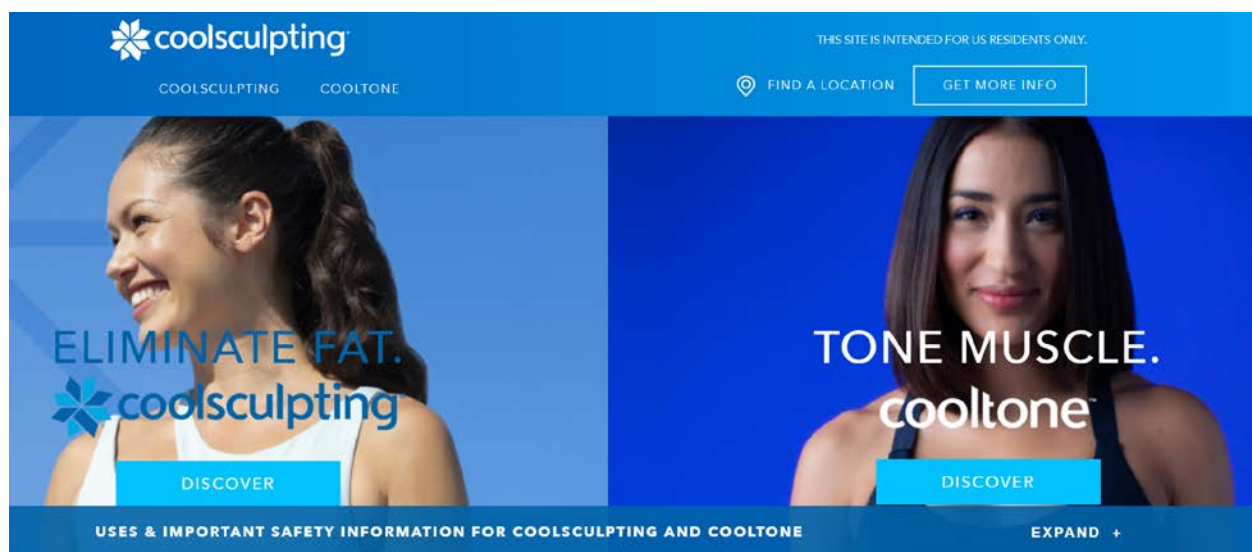
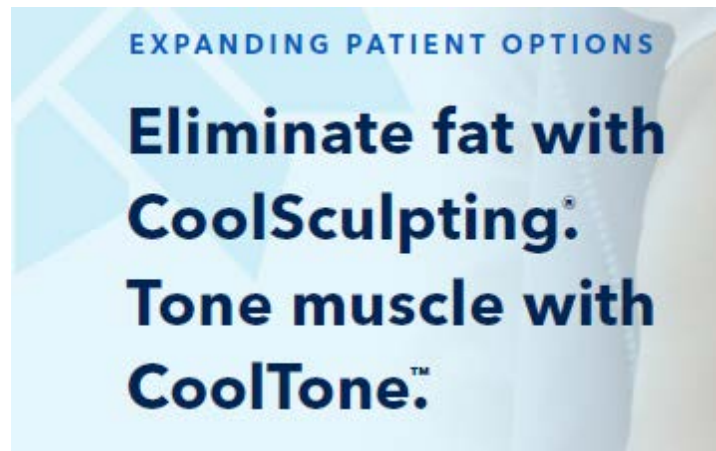
56. Allergan and Zeltiq import into the United States, offer for sale, and sell within the United States the CoolSculpting product and its components. *See* Exhibit 33; Exhibits 12–13. On information and belief, the CoolSculpting product administers a noninvasive procedure indicated for cold-assisted lipolysis (breakdown of fat) via thermal contact of the device with a patient's skin. *See* Exhibit 34; Exhibit 35.

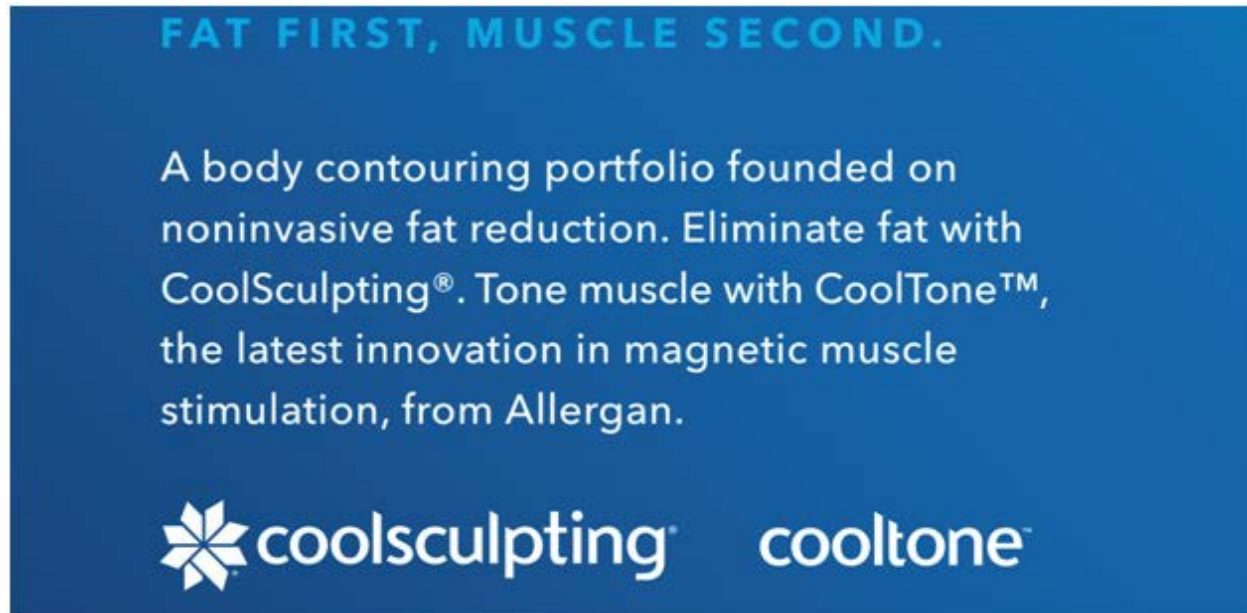
57. Zeltiq USA submitted a 510(k) premarket notification application to the FDA for the CoolSculpting product and its components. Exhibit 35. The 510(k) states: "The CoolSculpting System is a portable thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The CoolSculpting System consists of components such as a control unit, detachable vacuum and surface applicators, as well as supplies such as liners, gelpads, skin wipes, cycle cards, foam borders and securement system."

Id. Specifically, the CoolSculpting product uses a thermal treatment called cryolipolysis to freeze fat and kill fat cells. Exhibit 34. The CoolSculpting product includes a control unit and detachable applicators and treats at a target temperature down to about -10°C . *See* Exhibit 35.

58. On information and belief, using the CoolSculpting and CoolTone products in conjunction with one another, i.e., using a combination of magnetic and thermal treatments to tone a patient's muscles, infringes one or more claims of each the '575 and '895 patents. For example, claim 15 of the '575 patent recites "[t]he method of claim 9, further comprising cooling, by a cooling element at a temperature of between -15°C . and 10°C ." As another example, claim 5 of the '895 patent recites, "[t]he method of claim 1, further comprising cooling a skin of the patient by a cooling element have a temperature in a range of -20°C . to 20°C ."

59. On information and belief, Allergan and Zeltiq actively encourage, promote, provide instruction, and support the use of the CoolTone and CoolSculpting products, with the knowledge and intention that their customers will commit acts in such a manner that constitutes direct infringement of one or more claims of the '575 and '895 patents. For example, a CoolTone brochure advertises the use of the CoolTone product in conjunction with the CoolSculpting product with the slogan: "Eliminate fat with CoolSculpting®. Tone muscle with CoolTone™." Exhibit 2; *see also* Exhibit 36 (aesthetic professional's website encouraging CoolTone in conjunction with CoolSculpting). Allergan and Zeltiq's CoolSculpting website also advertises the CoolTone treatment in conjunction with the CoolSculpting treatment. Exhibit 33.





60. On information and belief, medical professionals directly infringe one or more claims of each of the '575 and '895 patents either literally or under the doctrine of equivalents when they treat patients using the CoolTone product in conjunction with the CoolSculpting product in accordance with Defendants' established treatment protocols. On information and belief, the CoolTone and CoolSculpting products operate using treatment cards that are required to run their pre-programmed protocols. On information and belief, the CoolTone and CoolSculpting products can provide treatment only by using these cards. On information and belief, these pre-programmed protocols, when enacted, necessarily practice one or more claims of each of the '575 and '895 patents either literally or under the doctrine of equivalents.

61. For example, on information and belief, Dr. Grant Stevens—founder and director of Marina Plastic Surgery, located in Marina del Rey, California—provides his patients treatments using the CoolTone product in conjunction with the CoolSculpting product. According to the website associated with Marina Plastic Surgery, Dr. Stevens offers these concomitant treatments because the "CoolTone compliments what you get from CoolSculpting.

Once fat cells are destroyed and eliminated by CoolSculpting, CoolTone can then target your muscles to strengthen and tone them for further body contouring. Both techniques are non-surgical and can be done during the same session (starting with CoolSculpting).” Exhibit 37.

What is the difference between CoolTone and CoolSculpting?



CoolTone compliments what you get from CoolSculpting. Once fat cells are destroyed and eliminated by CoolSculpting, CoolTone can then target your muscles to strengthen and tone them for further body contouring. Both techniques are non-surgical and can be done during the same session (starting with CoolSculpting), for a maximum punch against fat and the ultimate redefining of your body. This dynamic duo treatment can transform your physique. Call us today and find out about the new CoolTone treatment and what it can do for you.

62. On information and belief, Defendants have had notice of the Asserted Patents. BTL’s Emsculpt webpage states that the Emsculpt device “may be subject to one or more U.S. or foreign patents or pending applications” and links to a webpage that lists the patents associated with the Emsculpt device and its uses, located at <https://www.btl.net.com/patents>. And, on or about December 23, 2019, BTL’s European affiliate initiated infringement proceedings against Zimmer Germany at the District Court Munich I (Germany) based on BTL’s German Utility Model DE 20 2016 008 804 U1 directed to the Emsculpt device. Further, on December 26, 2019, BTL filed a patent infringement suit in the District of Delaware against Defendants, asserting two patents, U.S. Patent Nos. 10,478,634 and 10,493,293, which are related to the Asserted Patents. And, on information and belief, Defendants have monitored the prosecution of the Asserted Patents as related patents since at least December 26, 2019. At the latest, Defendants have been aware of the individual patents since their respective issue dates and have had knowledge of the Asserted Patents via this complaint.

63. Defendants’ importation into the United States, use, offer for sale, and sale within the United States of the Accused Products is continuing. Exhibit 7; Exhibits 12–13; *see also* Cienega Med Spa, <https://www.instagram.com/p/CB62gfYAjYr/?igshid=1ciw14v0khjmo> (June

26, 2020); Suzanne Bruce & Associates Dermatology, <https://www.instagram.com/p/CCJb5pljga9/?igshid=wnb1tciofx49> (July 2, 2020). Moreover, Defendants have continued to distribute product literature and website materials encouraging their customers and others to use their products in the customary and intended manner that infringes the Asserted Patents. *E.g.*, Exhibits 2, 8, 32, 38.

64. On information and belief, since they have had knowledge of the Asserted Patents, Defendants' infringement has been and continues to be willful.

65. BTL has been injured by Defendants' infringement of the Asserted Patents and will suffer irreparable harm unless Defendants are enjoined from infringing the Asserted Patents.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 10,632,321

66. BTL repeats and re-alleges paragraphs 1–65 as if fully set forth herein.

67. The CoolTone product and its components directly infringe the '321 patent, either literally or under the doctrine of equivalents.

68. Defendants have, and will continue to, directly infringe the '321 patent, either literally or under the doctrine of equivalents, including for example, claims 15 and 16, under 35 U.S.C. § 271(a) by using, offering to sell, or selling within the United States or importing into the United States the CoolTone product.

69. Defendants have, and will continue to, induce others to infringe, literally or under the doctrine of equivalents, one or more claims of the '321 patent, including for example, claims 1 and 8, under 35 U.S.C. § 271(b) by encouraging and facilitating others, *i.e.*, medical professionals, to perform infringing acts using the CoolTone product and its components with the specific intent and knowledge that performance of such actions will infringe the '321 patent. As an example, Defendants provide a User Manual for the CoolTone System that explicitly instructs

their customers to use the CoolTone product in a way that directly infringes the method claims of the '321 patent.

70. On information and belief, medical professionals necessarily directly infringe one or more claims of the '321 patent either literally or under the doctrine of equivalents when they treat patients using the CoolTone product and its components in accordance with the pre-programmed treatment protocols. On information and belief, the CoolTone product operates using treatment cards that are required to run CoolTone protocols. On information and belief, the CoolTone product can provide treatment only by using these cards. On information and belief, the pre-programmed treatment protocols, when enacted, necessarily practice one or more claims of the '321 patent either literally or under the doctrine of equivalents.

71. On information and belief, Defendants have had notice of the '321 patent since at least April 28, 2020, if not earlier. On information and belief, Defendants have, and will continue to intentionally encourage acts of direct infringement with knowledge of the '321 patent and knowledge that their acts are encouraging infringement.

72. Defendants have, and will continue to, contributorily infringe one or more claims of the '321 patent, including for example, claims 1 and 8, under 35 U.S.C. § 271(c) by their importation, offer to sell, and sale of the CoolTone product and its components in the United States.

73. On information and belief, Defendants are aware that the CoolTone product and its components are designed for use in the CoolTone product, embody a material part of the invention claimed in the '321 patent, and are not staple articles of commerce suitable for non-infringing use. On information and belief, the CoolTone product and its components have no substantial non-infringing use.

74. Defendants' infringement of the '321 patent has damaged, and continues to damage, BTL in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that BTL would have made but for Defendants' infringing acts as provided by 35 U.S.C. § 284.

75. Defendants' infringement of the '321 patent has been willful, since at least April 28, 2020. On information and belief, Defendants have been aware of the '321 patent since at least its issuance and have willfully infringed the '321 patent, knowing such conduct to be in violation of 35 U.S.C. § 271. On information and belief, Defendants will continue to willfully infringe the '321 patent.

76. BTL will suffer irreparable harm unless Defendants are enjoined from infringing the '321 patent.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 10,695,575

77. BTL repeats and re-alleges paragraphs 1–76 as if fully set forth herein.

78. Defendants have, and will continue to, induce others to infringe, literally or under the doctrine of equivalents, one or more claims of the '575 patent, including for example, claims 1 and 9, under 35 U.S.C. § 271(b) by encouraging and facilitating others, *i.e.*, medical professionals, to perform infringing acts using the CoolTone product and its components with the specific intent and knowledge that performance of such actions will infringe the '575 patent. As an example, Defendants provide a User Manual for the CoolTone System that explicitly instructs their customers to use the CoolTone product in a way that directly infringes the method claims of the '575 patent.

79. Defendants have, and will continue to, induce others to infringe, literally or under the doctrine of equivalents, one or more claims of the '575 patent, including for example, claim 15, under 35 U.S.C. § 271(b) by encouraging and facilitating others, *i.e.*, medical professionals,

to perform infringing acts using the CoolTone product and its components in conjunction with the CoolSculpting product and its components with the specific intent and knowledge that performance of such actions will infringe the '575 patent. *E.g.*, Exhibits 2, 33.

80. On information and belief, medical professionals necessarily directly infringe one or more claims of the '575 patent either literally or under the doctrine of equivalents when they treat patients using the Accused Products and their components in accordance with the pre-programmed treatment protocols. On information and belief, the Accused Products operate using treatment cards that are required to run treatment protocols. On information and belief, the Accused Products can provide treatment only by using these cards. On information and belief, the pre-programmed treatment protocols, when enacted, necessarily practice one or more claims of the '575 patent either literally or under the doctrine of equivalents.

81. On information and belief, Defendants have had notice of the '575 patent since at least June 30, 2020, if not earlier. On information and belief, Defendants have, and will continue to intentionally encourage acts of direct infringement with knowledge of the '575 patent and knowledge that their acts are encouraging infringement.

82. Defendants have, and will continue to, contributorily infringe one or more claims of the '575 patent, including for example, claims 1 and 9, under 35 U.S.C. § 271(c) by their importation, offer to sell, and sale of the CoolTone product and its components in the United States.

83. On information and belief, Defendants are aware that the CoolTone product and its components are designed for use in the CoolTone product, embody a material part of the invention claimed in the '575 patent, and are not staple articles of commerce suitable for non-

infringing use. On information and belief, the CoolTone product and its components have no substantial non-infringing use.

84. Defendants' infringement of the '575 patent has damaged, and continues to damage, BTL in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that BTL would have made but for Defendants' infringing acts as provided by 35 U.S.C. § 284.

85. Defendants' infringement of the '575 patent has been willful, since at least June 30, 2020. On information and belief, Defendants have been aware of the '575 patent since at least its issuance and have willfully infringed the '575 patent, knowing such conduct to be in violation of 35 U.S.C. § 271. On information and belief, Defendants will continue to willfully infringe the '575 patent.

86. BTL will suffer irreparable harm unless Defendants are enjoined from infringing the '575 patent.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 10,695,576

87. BTL repeats and re-alleges paragraphs 1–86 as if fully set forth herein.

88. The CoolTone product and its components directly infringe the '576 patent, either literally or under the doctrine of equivalents.

89. Defendants have, and will continue to, directly infringe the '576 patent, either literally or under the doctrine of equivalents, including for example, claims 1 and 8, under 35 U.S.C. § 271(a) by making, using, offering to sell, or selling within the United States or importing into the United States the CoolTone product.

90. Defendants' infringement of the '576 patent has damaged, and continues to damage, BTL in an amount yet to be determined, of at least a reasonable royalty and/or lost

profits that BTL would have made but for Defendants' infringing acts as provided by 35 U.S.C. § 284.

91. Defendants' infringement of the '576 patent has been willful, since at least June 30, 2020. On information and belief, Defendants have been aware of the '576 patent since at least its issuance and have willfully infringed the '576 patent, knowing such conduct to be in violation of 35 U.S.C. § 271. On information and belief, Defendants will continue to willfully infringe the '576 patent.

92. BTL will suffer irreparable harm unless Defendants are enjoined from infringing the '576 patent.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 10,709,894

93. BTL repeats and re-alleges paragraphs 1–92 as if fully set forth herein.

94. The CoolTone product and its components directly infringe the '894 patent, either literally or under the doctrine of equivalents.

95. Defendants have, and will continue to, directly infringe the '894 patent, either literally or under the doctrine of equivalents, including for example, claims 1 and 9, under 35 U.S.C. § 271(a) by making, using, offering to sell, or selling within the United States or importing into the United States the CoolTone product.

96. Defendants' infringement of the '894 patent has damaged, and continues to damage, BTL in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that BTL would have made but for Defendants' infringing acts as provided by 35 U.S.C. § 284.

97. Defendants' infringement of the '894 patent has been willful, since at least July 14, 2020. On information and belief, Defendants have been aware of the '894 patent since at least its issuance and have willfully infringed the '894 patent, knowing such conduct to be in

violation of 35 U.S.C. § 271. On information and belief, Defendants will continue to willfully infringe the '894 patent.

98. BTL will suffer irreparable harm unless Defendants are enjoined from infringing the '894 patent.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 10,709,895

99. BTL repeats and re-alleges paragraphs 1–98 as if fully set forth herein.

100. The CoolTone product and its components directly infringe the '895 patent, either literally or under the doctrine of equivalents.

101. Defendants have, and will continue to, directly infringe the '895 patent, either literally or under the doctrine of equivalents, including for example, claims 6 and 14, under 35 U.S.C. § 271(a) by making, using, offering to sell, or selling within the United States or importing into the United States the CoolTone product.

102. Defendants have, and will continue to, induce others to infringe, literally or under the doctrine of equivalents, one or more claims of the '895 patent, including for example, claim 1, under 35 U.S.C. § 271(b) by encouraging and facilitating others, *i.e.*, medical professionals, to perform infringing acts using the CoolTone product and its components with the specific intent and knowledge that performance of such actions will infringe the '895 patent. Specifically, Defendants provide a User Manual for the CoolTone System that explicitly instructs their customers to use the CoolTone product in a way that directly infringes the method claims of the '895 patent.

103. Defendants have, and will continue to, induce others to infringe, literally or under the doctrine of equivalents, one or more claims of the '895 patent, including for example, claim 5, under 35 U.S.C. § 271(b) by encouraging and facilitating others, *i.e.*, medical professionals, to perform infringing acts using the CoolTone product and its components in conjunction with the

CoolSculpting product and its components with the specific intent and knowledge that performance of such actions will infringe the '895 patent. *E.g.*, Exhibits 2, 33.

104. On information and belief, medical professionals necessarily directly infringe one or more claims of the '895 patent either literally or under the doctrine of equivalents when they treat patients using the Accused Products and their components in accordance with the pre-programmed treatment protocols. On information and belief, the Accused Products operate using treatment cards that are required to run treatment protocols. On information and belief, the Accused Products can provide treatment only by using these cards. On information and belief, the pre-programmed treatment protocols, when enacted, necessarily practice one or more claims of the '895 patent either literally or under the doctrine of equivalents.

105. On information and belief, Defendants have had notice of the '895 patent since at least July 14, 2020, if not earlier. On information and belief, Defendants have, and will continue to intentionally encourage acts of direct infringement with knowledge of the '895 patent and knowledge that their acts are encouraging infringement.

106. Defendants have, and will continue to, contributorily infringe one or more claims of the '895 patent, including for example, claim 1, under 35 U.S.C. § 271(c) by their importation, offer to sell, and sale of the CoolTone product and its components in the United States.

107. Defendants' infringement of the '895 patent has damaged, and continues to damage, BTL in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that BTL would have made but for Defendants' infringing acts as provided by 35 U.S.C. § 284.

108. Defendants' infringement of the '895 patent has been willful, since at least July 14, 2020. On information and belief, Defendants have been aware of the '895 patent since at

least its issuance and have willfully infringed the '895 patent, knowing such conduct to be in violation of 35 U.S.C. § 271. On information and belief, Defendants will continue to willfully infringe the '895 patent.

109. BTL will suffer irreparable harm unless Defendants are enjoined from infringing the '895 patent.

PRAYER FOR RELIEF

WHEREFORE, BTL requests entry of judgment against Defendants as follows:

- A. A judgment that Defendants have infringed one or more claims of the Asserted Patents in violation of 35 U.S.C. § 271(a)–(c);
- B. An order permanently enjoining Defendants, its officers, directors, employees, agents, and all persons acting in concert with them, from infringing the Asserted Patents;
- C. An award of damages for infringement of the Asserted Patents, with prejudgment interest and costs, said damages to be trebled by reason of the intentional and willful nature of Defendants' infringement, as provided by 35 U.S.C. § 284;
- D. A judgment that Defendants have willfully infringed one or more claims of the Asserted Patents;
- E. A determination that this case is “exceptional” under 35 U.S.C. § 285, and an award of BTL's reasonable attorneys' fees;
- F. An award of pre- and post-judgment interest of any monetary damages at the highest rate allowed by law;
- G. An award of BTL's costs and expenses in this action; and
- H. For such other relief as the Court may deem just and proper.

JURY DEMAND

Under Rule 38 of the Federal Rules of Civil Procedure, Plaintiff BTL Industries, Inc.
respectfully demands a trial by jury of any issues triable of right by a jury.

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Dated: August 5, 2020

/s/ Nathan R. Hoeschen

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